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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,467	09/24/2008	Kie-Bong Nahm	HANOL-12053	5890
72960	7590	09/24/2010	EXAMINER	
Casimir Jones, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562			BELLAMY, TAMIKO D	
			ART UNIT	PAPER NUMBER
			2856	
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			09/24/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,467	<b>Applicant(s)</b> NAHM ET AL.	
	<b>Examiner</b> TAMIKO D. BELLAMY	<b>Art Unit</b> 2856	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/22/10; 9/10/09</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings*

1. Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. **See page 14, where applicant indicates the figures are convention lateral flow quantitative assay strip.**

### *.Specification*

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. The disclosure is objected to because of the following informalities:

- a. Pg, 74, line 14, please change "1 to 9" to -- 3 to 9--. The applicant discloses that figs. 1 and 2 are conventional. Therefore figs. 3-9, are the present invention. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Re claim 1, Pg. 117, lines 11, 12, and 14, the words “analyte/labeled” are vague and unclear as to whether the applicant is claiming an analyte detector or a labeled detector.

Re claim 1, Pg. 117, line 16, the word “detector” is vague and unclear as to which detector the applicant is referring to. The applicant discloses an analyte detector and labeled detector in the previous lines.

Re claim 1, Pg. 117, line 18, the words “labeled detector/analyte/unlabeled” are vague and unclear as to whether the applicant is claiming a labeled detector captor, an analyte captor, or an unlabeled captor.

Re claim 1, Pg. 118, lines 7 and 10, the words “detector/analyte” are vague and unclear as to whether the applicant is claiming a detector conjugate or analyte conjugate.

Re claim 1, Pg. 118, line 13, the words “labeled detector/analyte/unlabeled” are vague and unclear as to whether the applicant is claiming a labeled detector captor, an analyte captor, or an unlabeled captor.

Re claim 5, Pg. 121, line 21; Pg. 122, line 1, the word “detector” is vague and unclear as to which detector the applicant is referring to. The applicant discloses a reference detector and a labeled detector.

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Re claim 5, Pg. 122, lines 12, the words “labeled detector/analyte/unlabeled” are vague and unclear as to whether the applicant is claiming a labeled detector captor, an analyte captor, or an unlabeled captor.

Re claim 5, pg. 122, line 14, the words “reference detector/reference” is vague and unclear as to what the applicant is claiming.

Re claim 5, pg. 122, line 14, the words "material/unlabeled reference" are vague and unclear as to whether the applicant is claiming a material reference captor or an unlabeled reference captor.

Re claim 9, pg. 126, line 18, the words “labeled detector/analyte/unlabeled” are vague and unclear as to whether the applicant is claiming a labeled detector captor, an analyte captor, or an unlabeled captor.

Re claim 9, pg. 126, line 20, the words “reference detector/reference” is vague and unclear as to what the applicant is claiming.

Re claim 5, pg. 126, line 21, the words "material/unlabeled reference" are vague and unclear as to whether the applicant is claiming a material reference captor or an unlabeled reference captor.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 5 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,371,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because cover the same scope of the invention.

Re claim 5, ref. '582 discloses in claim 1, a sample pad adhered to one end of the backing and to which the sample is applied. A chromatography medium is adhered to the backing such that one end of the conjugate releasing pad farthest from the end of the strip to which the sample

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is applied. The farthest end of the strip to which the sample is applied, is equivalent to an opposite end of the backing. An absorption pad absorbs the sample. A detector is attached to the conjugate releasing pad. A reference detector is labeled with a fluorescent material identical to that used in labeling the detector. A captor is immobilized in lines within a viewing window. An unlabeled reference captor is different from the detector. An amount of analyte is determined by passing a laser. **Ref. '582 does not specifically state that the conjugate releasing pad is adhered to the backing in such a way that one end of the sample pad, close to an opposite end of the backing, overlaps with an end of the conjugate releasing pad to which a labeled detector is attached.** However, ref. 582 discloses that a conjugate releasing pad is adhered to the backing such that one end of the sample pad overlaps with the end of the conjugate releasing pad closest to the end of the strip to which the sample is applied and upon which the label detector is releasably attached. This teaching clearly infers and/or suggests that the sample pad, close to the opposite end of the backing. It would have been obvious to one of ordinary skill in the art at the time of the invention to configure a conjugate releasing pad as claimed for the purpose of forming a conjugate.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Nahm et al. (7,371,582).

The applied reference has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Re claim 1, Nahm et al. discloses applying a liquid sample to one end of a chromatography medium. The liquid sample is migrated through the chromatography medium to react to an analyte with a labeled detector. Nahm et al. also discloses an analyte/labeled detector and a labeled detector/analyte/unlabeled captor triple conjugate as claimed. The amount of analytes is determined by passing a laser as claimed (Col. 3, lines 17-65; Col. 4, lines 1-12; Col. 28, lines 1-41).

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMIKO D. BELLAMY whose telephone number is (571)272-2190. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hezron Williams/  
Supervisory Patent Examiner, Art Unit  
2856

Tamiko Bellamy  
/TB/  
September 2, 2010